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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,568	08/03/2001	Udo Baron	BBI-088CPADV2	9670

959 7590 03/25/2003

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/922,568

Applicant(s)

BARON ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 32-50 are pending in the application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 32-40, 43, 44, 47 and 48, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a wild type Tet repressor operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.
- II. Claims 32-39, 41, 43, 45, 47 and 49, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a mutated Tet repressor operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.
- III. Claims 32-39, 42, 43, 46, 47 and 50, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a GAL4 operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.

- IV. Claims 32-39, 42, 43, 46, 47 and 50, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a LexA operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.
- V. Claims 32-39, 42, 43, 46, 47 and 50, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a LacR operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.
- VI. Claims 32-39, 42, 43, 46, 47 and 50, drawn to a transgenic organism comprising a transgene comprising a nucleic acid molecule encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide encoding a steroid hormone receptor operatively linked to a second polypeptide comprising at least one copy of a mutated acidic region of HSV VP16, classified in class 800, subclass 8.

The inventions are distinct, each from the other for following reasons.

The inventions of Groups I-VI are patentably distinct because the inventions are drawn to materially distinct compositions. The transgenic organism of Groups I-VI comprises different transgenes in its genome, hence, is chemically, biologically and functionally distinct from each other. Therefore, the inventions of Groups I-VI are patentably distinct from each other.

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Groups I-VI are comprised of multiple inventions which are the products drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. If any of Groups I-VI are elected, applicants must elect a single invention which is the product drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
March 20, 2003

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER